

POLICY LEVEL

PL-P2 Hepatitis C Treatment Expansion

RECOMMENDATION SUMMARY TEXT

The Health Care Authority (HCA) requests \$77,738,000 (\$20,019,000 GF-State) in the 2016 Supplemental to expand treatment for hepatitis C virus (HCV) to Medicaid clients with less severe liver disease. Given that overall hepatitis C treatment costs are trending lower than anticipated, and that many persons with less severe disease would benefit from treatment, the HCA requests additional resources to expand treatment for hepatitis C to Medicaid clients with less severe liver disease. If approved, this request would extend HCV treatment to approximately 4,700 additional Medicaid patients with less severe liver disease.

PACKAGE DESCRIPTION

Through July 2015, Medicaid HCV expenditures have been less than budgeted. Analyses suggest persons with HCV are not coming into care as rapidly as anticipated; or, it is possible the prevalence of severe liver disease in the Medicaid population was over estimated in the original model. The Medicaid HCV coverage policy was created to ensure patients with HCV who are at the highest risk for liver-related complications received treatment first, therefore the policy limits treatment to those with severe liver disease. The June 2015 update of the *Infectious Disease Society of America (IDSA) and the American Association of the Study of Liver Disease (AASLD) Recommendations for Testing, Managing, and Treating Hepatitis C* strongly encourages treating everyone with HCV before the onset of severe liver disease and other complications. Furthermore, evidence shows that curing HCV reduces all-cause mortality and liver-related adverse consequences, including end-stage liver disease, hepatocellular carcinoma, and transplant.

The current Medicaid hepatitis C clinical policy treats persons with severe liver disease. The initial policy estimated the number of Medicaid persons infected with the hepatitis C virus; the prevalence of severe liver disease in this population; and the rate at which persons would be identified, staged and treated. Actual experience indicates that persons with hepatitis C are being identified and entering into treatment at a rate slower than initially anticipated. In addition, the cost of the newer more effective hepatitis C medications, while still extraordinarily expensive, is less than initially modeled.

Hepatitis C is a chronic viral infection of the liver that affects approximately 1 percent of the U.S. population, or over three million people. In Washington State, estimates are that 75,000 to 100,000 people are infected with hepatitis C. If untreated, about 35 percent of patients infected will develop chronic liver disease, cirrhosis, or liver cancer over a time span of 20 to 30 years.

Liver scarring (i.e. fibrosis) caused by hepatitis C is categorized along a continuum, from absent (F0) to severe (F4, which equates to cirrhosis). The more severe a person's fibrosis, the more likely they are to develop complications, and possibly die of their disease.

Advances in the treatment of hepatitis C have led to the availability of highly effective and safe medications that are administered orally either once or twice daily. These medications are cost-effective at a population level as measured by the cost per quality adjusted life year gained. Although the high prevalence of infection and the cost of treating a single individual (the Average Wholesale Price for a treatment course is approximately \$85,000 to \$95,000) initially made treating all patients with chronic hepatitis C infection cost prohibitive, additional medications to treat hepatitis C have been approved by the FDA resulting in price competition in the market place. Albeit still expensive, these treatments are now much more affordable.

The IDSA/AASLD have developed authoritative guidelines for the treatment of hepatitis C. Per the August 2015 update of the IDSA/AASLD guidelines, everyone with chronic hepatitis C infection should be treated; however, based on available resources, immediate treatment should be prioritized as necessary so that the “highest priority” persons with severe liver disease (F3 or F4) are treated first followed by “high priority” patients, those with significant liver disease (F2). Based on these IDSA/AASLD recommendations, and recognizing the reality of constrained resources, the HCA developed a treatment policy that prioritizes persons with F3-F4 fibrosis, or persons with F2 fibrosis who are co-infected with the Human Immunodeficiency Virus (HIV) or hepatitis B.

In 2015, based on estimates of the prevalence of hepatitis C infection in the Medicaid population; the proportion of persons thought to have F3-F4 disease; and the rate at which patients would come into care, the HCA requested and the legislature appropriated funding for hepatitis C treatment. Through July 2015, hepatitis C expenditures have been less than budgeted. Analyses of available data suggest that persons with hepatitis C are not coming into care as rapidly as was anticipated; in addition, it is possible that the prevalence of F3-F4 disease in the Medicaid population is less than estimated. Finally, supplemental rebates for the preferred hepatitis C treatments, which were finalized after the development and implementation of the HCA’s clinical policy, provide the state with a considerable discount for the preferred medications, Harvoni and Sovaldi.

Kate LaBelle, Financial Services: 360-725-1846 or kate.labelle@hca.wa.gov

Daniel Lessler, MD, Chief Medical Officer: 360-725-1612 or daniel.lessler@hca.wa.gov

FISCAL DETAILS/OBJECTS OF EXPENDITURE

	FY 2016	FY 2017	Total
1. Operating Expenditures:			
Fund 001-1 GF-State	\$ 6,189,000	\$ 13,830,000	\$ 20,019,000
Fund 001-C GF-Federal Medicaid Title XIX	\$ 18,605,000	\$ 39,114,000	\$ 57,719,000
Total	\$ 24,794,000	\$ 52,944,000	\$ 77,738,000
	FY 2016	FY 2017	Total
2. Staffing:			
Total FTEs	-	-	-

	FY 2016	FY 2017	Total
3. Objects of Expenditure:			
A - Salaries And Wages	\$ -	\$ -	\$ -
B - Employee Benefits	\$ -	\$ -	\$ -
C - Personal Service Contracts	\$ -	\$ -	\$ -
E - Goods And Services	\$ -	\$ -	\$ -
G - Travel	\$ -	\$ -	\$ -
J - Capital Outlays	\$ -	\$ -	\$ -
N - Grants, Benefits & Client Services	\$ 24,794,000	\$ 52,944,000	\$ 77,738,000
Other (specify) -	\$ -	\$ -	\$ -
Total	\$ 24,794,000	\$ 52,944,000	\$ 77,738,000
	FY 2016	FY 2017	Total
4. Revenue:			
Fund 001-C GF-Federal Medicaid Title XIX	\$ 18,605,000	\$ 39,114,000	\$ 57,719,000
Total	\$ 18,605,000	\$ 39,114,000	\$ 57,719,000

NARRATIVE JUSTIFICATION

WHAT SPECIFIC PERFORMANCE OUTCOMES DOES THE AGENCY EXPECT?

Over the course of the biennium, it is now estimated that 4,301 clients with chronic hepatitis C underwent treatment. In the original 2015-2017 biennium budget, the state originally estimated 3,913 would have gone through treatment during that same period. The HCA is requesting that the underspent funds be used to expand the availability to hepatitis C treatment.

PERFORMANCE MEASURE DETAIL

Activity Inventory

H005 HCA National Health Reform

H011 HCA All Other Clients – Fee for Service – Mandatory Services

IS THIS DECISION PACKAGE ESSENTIAL TO IMPLEMENT A STRATEGY IDENTIFIED IN THE AGENCY'S STRATEGIC PLAN?

Yes. The HCA's strategic plan emphasizes the triple aim: better population health, more effective care, and lower costs. Effective treatment of hepatitis C will improve population health.

DOES THIS DECISION PACKAGE PROVIDE ESSENTIAL SUPPORT TO ONE OR MORE OF THE GOVERNOR'S RESULTS WASHINGTON PRIORITIES?

Yes. This strategy supports Goal 4.1.2: Decrease the proportion of adults reporting fair or poor health from 15 percent to 14 percent by 2014. Patients with chronic hepatitis C who develop cirrhosis and its complications are likely to report overall poor health status. By treating chronic hepatitis C, patients will avoid adverse health consequences, and be more likely to report better health status.

WHAT ARE THE OTHER IMPORTANT CONNECTIONS OR IMPACTS RELATED TO THIS PROPOSAL?

The state originally adopted criteria that provide treatment to persons with severe liver disease (F3 or F4) as a means of assuring that those most at risk for complications from hepatitis C were treated. Given that the number of individuals that have received treatment are lower than originally anticipated, this request proposes to use the anticipated savings to expand treatment availability to persons with less severe disease who are at relatively high risk of disease progression.

WHAT ALTERNATIVES WERE EXPLORED BY THE AGENCY, AND WHY WAS THIS ALTERNATIVE CHOSEN?

An option would be to continue the existing policy of only treating individuals with severe liver disease (F3 or F4). However, the HCA elects to offer an expanded treatment policy that closer aligns to the guidelines of the IDSA/AASLD. Such a strategy will further reduce hepatitis C morbidity, and reduce the population reservoir of hepatitis C, thus contributing to decreased hepatitis C transmission.

WHAT ARE THE CONSEQUENCES OF NOT ADOPTING THIS PACKAGE?

It is better to treat disease before complications occur. This request proposes that the state expand its hepatitis C treatment criteria so as to treat clients before their condition progresses to severe liver disease. If this proposal is not adopted, a greater proportion of people chronically infected with hepatitis will be at risk of experiencing hepatitis C related morbidity and mortality. In addition, the rate of spread of hepatitis C will not be abated.

WHAT IS THE RELATIONSHIP, IF ANY, TO THE STATE CAPITAL BUDGET?

None

WHAT CHANGES WOULD BE REQUIRED TO EXISTING STATUTES, RULES, OR CONTRACTS TO IMPLEMENT THE CHANGE?

None

EXPENDITURE AND REVENUE CALCULATIONS AND ASSUMPTIONS

REVENUE CALCULATIONS AND ASSUMPTIONS:

The HCA assumes that the Medicaid services funded by this proposal will be eligible for federal matching funds. The exact amount of federal funds depends on the mix of newly eligible adults and non-newly eligible clients receiving treatment.

Payment of treatment for non-newly eligible clients would receive the federal medical assistance percentage (FMAP). There are two federal payment percentages that impact the newly eligible federal fund match rate: the newly eligible FMAP rate and the presumptive Supplemental Security Income (SSI) federal match rate. Presumptive SSI eligible clients make up part of the overall newly eligible group and

receive a unique federal match rate. The federal matching fund rates used to estimate federal funds are provided in the table below.

Federal Matching Funds Rate Assumption		
	Fiscal Year 2016	Fiscal Year 2017
Non-newly eligible FMAP	50.08%	50.10%
Newly eligible combined	99.18%	96.94%
Presumptive SSI	82.53%	85.53%
Newly eligible FMAP	100%	97.5%

See backup document.

EXPENDITURE CALCULATIONS AND ASSUMPTIONS:

The first step in determining the fiscal impact of new hepatitis C treatment is to estimate the number of Medicaid clients with hepatitis C. Prevalence rates of hepatitis C were estimated by age/gender groups. Two approaches were used in calculating these rates; one for newly eligible adults, and another for non-newly eligible clients:

An analysis of the prevalence rate of hepatitis C was conducted for clients just prior to open enrollment in September 2013. This time period was selected to avoid any influence of the Affordable Care Act (ACA), and to isolate the prevalence rate among non-newly eligible clients.

Separate prevalence rates were computed because there is ample historical data for the non-newly eligible population for which to base assumptions. However, many newly eligible clients are new to Medicaid and there is little data to base an inference of hepatitis C prevalence. In addition to data limitations, evidence suggests that there are many hepatitis C positive non-newly eligible clients who are on disability and eligible as Categorically Needy disabled adults. This means that there are likely clients who are enrolled in Medicaid because they have chronic hepatitis C, or have inflections that correlate with having hepatitis C. These prevalence rates exclude Medicaid dual eligible clients and clients with a scope of service that doesn't cover hepatitis C treatment.

Medicaid drug acquisition prices are based on actual experience since treatment has already begun. An analysis of historical hepatitis C drug purchasing patterns revealed that about 12 percent of pharmaceuticals for hepatitis C treatment were purchased through a participating 340b provider.¹ It is assumed that this pattern will persist and that the remaining 88 percent of pharmaceuticals would be purchased at the payment rate and will be partially offset by a drug rebate.

Cost-offsets

¹ The 340b Drug Pricing Program allows certain hospitals and other health care providers to obtain discounted prices on prescription drugs and biologics (other than vaccines) from drug manufacturers.

To estimate future avoided costs as a result of more effective hepatitis C treatment, a cost-offset model was developed. The cost-offset model uses a cohort approach to identify non-dual adult CN Blind/Disabled clients for which at least one claim exists in calendar year 2006 with a hepatitis C diagnosis code. Any client identified with an advanced liver disease in calendar year 2006 is excluded from the cohort.

Two sub-populations are identified and analyzed:

- Chronic condition sub-population: Clients who develop an advanced liver disease between calendar years 2007 and 2011 inclusive;
- Reference sub-population: Clients who do not experience an advanced liver condition over calendar years 2007 to 2011.

Based on the above sub-populations, trended per-member per month costs are calculated into fiscal year 2017 based on rough historical cost trends from calendar years 2007 to 2010. This analysis accounts for attrition off of the sub-population due to: (1) mortality, (2) dual eligibility status, and (3) loss of Medicaid coverage. Also, any member months and costs in which capitation payments are made for the client are eliminated.

An assumed adherence and effectiveness rates for the chronic condition sub-population are applied and assumed that those who are treated effectively will have per-member per month experiences similar to the reference sub-population.

See backup document.

DISTINCTION BETWEEN ONE-TIME AND ONGOING COSTS:

Costs are expected to be ongoing.

BUDGET IMPACTS IN FUTURE BIENNIA:

Hepatitis C treatment will continue to be offered in future biennia.